

REMARKS/ARGUMENTS

Reconsideration of this Application and entry of this Amendment are respectfully requested. Claims 1, 3-6, and 8-25 are pending in the present Application. In the Office Action dated July 29, 2009, the Examiner rejected pending claims 1, 3-6, and 8-25 on various grounds. Claims 1, 6, 11, 18, and 22 are amended herein. In view of the amendments and following remarks, favorable consideration and allowance of the Application is respectfully requested.

35 U.S.C. §102 Rejections

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the . . . claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Thus, to warrant the §102 rejection, the references cited by the Examiner must show each and every limitation of the claims in complete detail. The Applicant respectfully asserts that the cited reference fails to do so.

- A. Claims 1, 3-6, and 8-10 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Pat. No. 6,616,765 to Castro, *et al.* (the *Castro* patent).

The Applicant respectfully asserts that the *Castro* patent fails to teach or suggest all the claim limitations.

The *Castro* patent fails to disclose, teach, or suggest:

a stent delivery system including a stent having a plurality of end-to-end cylindrical stent segments, the axes of the plurality of cylindrical stent segments lying along a longitudinal axis of the stent, the stent having a first region continuous across at least one pair of the longitudinally adjacent cylindrical stent segments and a second region continuous across at least one pair of the longitudinally adjacent cylindrical stent segments; and a coating including a first coating section comprising a first polymer and a second coating section comprising a second polymer; wherein: the first coating section is disposed on and completely covers the outer surface in the first region of the longitudinally adjacent cylindrical stent segments; and the second coating section is

disposed on and completely covers the outer surface in the second region of the longitudinally adjacent cylindrical stent segments; and the first region and the second region are discrete, and the first coating section and the second coating section are discrete, as recited in independent claim 1; or

a coated stent including a stent having a plurality of end-to-end cylindrical stent segments, the axes of the plurality of cylindrical stent segments lying along a longitudinal axis of the stent, the stent having a first region continuous across at least one pair of the longitudinally adjacent cylindrical stent segments and a second region continuous across at least one pair of the longitudinally adjacent cylindrical stent segments; and a coating including a first coating section comprising a first polymer and a second coating section comprising a second polymer; wherein: the first coating section is disposed on and completely covers the outer surface in the first region of the longitudinally adjacent cylindrical stent segments; and the second coating section is disposed on and completely covers the outer surface in the second region of the longitudinally adjacent cylindrical stent segments; and the first region and the second region are discrete, and the first coating section and the second coating section are discrete, as recited in independent claim 6.

At most, the *Castro* patent discloses a patterned coating on a prosthesis, for example a stent, and a method for forming the coating, plus an apparatus for forming the patterned coating. *See Abstract.* The Applicant respectfully notes that “stent segment” as claimed and as used consistently through the specification of the present Application refers to the segments forming the stent, such as the cylindrical W-shaped stent segments 160 illustrated in Figures 2-4. While the specification is not to be read into the claims, the verbiage of the claims must be considered to possess their ordinary usage as would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in applicant's specification. *See MPEP 2111.* The *Castro* patent fails to include “stent segment” or “segment,” but at most refers to a strut 68 of the prosthesis 12. See Figures 6A, 7-15; column 14, lines 58-61.

Claims 3-5 and claims 8-10 depend directly or indirectly from independent claims 1 and 6, respectively, and so include all the elements and limitations of their respective independent claims. The Applicant therefore submits that the dependent claims are allowable over the *Castro* patent for at least the same reasons as set forth above with respect to their independent claims.

Withdrawal of the rejection of claims 1, 3-6, and 8-10 under 35 U.S.C. §102(e) as being anticipated by the *Castro* patent is respectfully requested.

35 U.S.C. §103 Rejections

Obviousness is a question of law, based on the factual inquiries of 1) determining the scope and content of the prior art; 2) ascertaining the differences between the claimed invention and the prior art; and 3) resolving the level of ordinary skill in the pertinent art. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). See MPEP 2143.03. The Applicants respectfully assert that the cited reference fails to teach or suggest all the claim limitations.

B. Claims 11-25 were rejected under 35 U.S.C. §103(a) as being unpatentable over the *Castro* patent.

The Applicant respectfully asserts that the *Castro* patent fails to teach or suggest all the claim limitations.

The *Castro* patent fails to disclose, teach, or suggest:

a method for producing a coated stent including providing a stent having a plurality of end-to-end cylindrical stent segments, the axes of the plurality of cylindrical stent segments lying along a longitudinal axis of the stent, the stent having a first region continuous across at least one pair of longitudinally adjacent cylindrical stent segments and a second region continuous across at least one pair of longitudinally adjacent cylindrical stent segments; mixing a first polymer and first therapeutic agent with a first solvent to form a first polymer solution; applying the first polymer solution to the first region to form a first coating section of a coating completely covering the outer surface in the first region of the longitudinally adjacent cylindrical stent segments; mixing a second polymer and second therapeutic agent with a second solvent to form a second

polymer solution; and applying the second polymer solution to the second region to form a second coating section of the coating completely covering the outer surface in the second region of the longitudinally adjacent cylindrical stent segments, wherein the first coating section and the second coating section are discrete, and the first region has a longitudinal length greater than the diameter of the stent in an expanded state, as recited in independent claim 11;

a system for producing a coated stent from a stent having a plurality of end-to-end cylindrical stent segments, the axes of the plurality of cylindrical stent segments lying along a longitudinal axis of the stent, the stent having a first region continuous across at least one pair of the longitudinally adjacent cylindrical stent segments and a second region continuous across at least one pair of the longitudinally adjacent cylindrical stent segments, including: means for mixing a first polymer and first therapeutic agent with a first solvent to form a first polymer solution; means for applying the first polymer solution to the first region to form a first coating section of a coating completely covering the outer surface in the first region of the longitudinally adjacent cylindrical stent segments; means for mixing a second polymer and second therapeutic agent with a second solvent to form a second polymer solution; and means for applying the second polymer solution to the second region to form a second coating section of the coating completely covering the outer surface in the second region of the longitudinally adjacent cylindrical stent segments, wherein the first coating section and the second coating section are discrete, and the first region has a longitudinal length greater than the diameter of the stent in an expanded state, as recited in independent claim 18; or

a coated stent including a stent having a plurality of end-to-end cylindrical stent segments, the axes of the plurality of cylindrical stent segments lying along a longitudinal axis of the stent, the stent having a discrete first region continuous across at least one pair of the longitudinally adjacent cylindrical stent segments and a discrete second region continuous across at least one pair of the longitudinally adjacent cylindrical stent segments; a first polymer including a first therapeutic agent, the first polymer disposed on and completely covering the outer surface in the discrete first region of the longitudinally adjacent cylindrical stent segments as a first coating section of a coating; and a second polymer including a second therapeutic agent, the second polymer disposed

on and completely covering the outer surface in the discrete second region of the longitudinally adjacent cylindrical stent segments as a second coating section of the coating, wherein the first coating section and the second coating section are discrete, and the discrete first region has a longitudinal length greater than the diameter of the stent in an expanded state, as recited in independent claim 22.

At most, the *Castro* patent discloses a patterned coating on a prosthesis, for example a stent, and a method for forming the coating, plus an apparatus for forming the patterned coating. *See Abstract.* The Applicant respectfully notes that “stent segment” as claimed and as used consistently through the specification of the present Application refers to the segments forming the stent, such as the cylindrical W-shaped stent segments 160 illustrated in Figures 2-4. While the specification is not to be read into the claims, the verbiage of the claims must be considered to possess their ordinary usage as would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in applicant's specification. *See MPEP 2111.* The *Castro* patent fails to include “stent segment” or “segment,” but at most refers to a strut 68 of the prosthesis 12. See Figures 6A, 7-15; column 14, lines 58-61.

Claims 12-17; claims 19-21; and claims 23-25 depend directly or indirectly from independent claims 11, 18, and 22, respectively, and so include all the elements and limitations of their respective independent claims. The Applicant therefore submits that the dependent claims are allowable over the *Castro* patent for at least the same reasons as set forth above with respect to their independent claims.

Withdrawal of the rejection of claims 11-25 under 35 U.S.C. §103(a) as being unpatentable over the *Castro* patent is respectfully requested.

Conclusion

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 543-0221.

Respectfully submitted,

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